REMARKS

I. APPLICANTS' INVENTION

The present invention relates to a catheter balloon made of tube having a microstructure of nodes and fibrils such as porous expanded polytetrafluoroethylene (PTFE), further including a non-porous coating over the porous microstructure. The coating renders the balloon non-porous and thereby able to contain a desired inflating media (e.g., air or saline fluid). The thinness, flexibility and strength of the construction allow the resulting balloon to be collapsed to a small first diameter for insertion into a vascular conduit to a desired location at which it can be inflated to the maximum diameter of the tube in the fashion of a conventional polyethylene terephthalate (PET) catheter balloon. The balloon of the present invention is superior to such conventional balloons due to its flexibility, thinness, strength and lubricious materials.

II. PRELIMINARY REMARKS

Claims 1-9 and 11-20 are pending in the present application. All claims stand rejected under 103(a).

III. REJECTION OF CLAIMS 1-9 AND 11-20 UNDER 35 USC 103(A) AS UNPATENTABLE OVER McWHORTER, US PATENT 4,106,509 IN VIEW OF KARWOSKI et al., US PATENT 4,718,907.

McWhorter discloses a balloon catheter comprising a tubular shaft having proximal and distal ends and having an inflatable balloon affixed to the distal end thereof. The Examiner references McWhorter at col. 3, lines 10-22 wherein McWhorter teaches that the tubular shaft (NOT the balloon) of his balloon catheter may be made from porous expanded PTFE (see also col. 2, lines 63 to col. 3, line 9 and Figure 1, ref. no. 38).

Contrary to the Examiner's assertion that the balloon of McWhorter is an inelastic balloon, McWhorter clearly teaches that "Balloon 28 is similar to inflation balloons used in conventional catheters. It is *elastomeric* (in the preferred embodiment, elastomeric silicone rubber)..." (col. 3, lines 37-39, emphasis added).

While it is clear that the balloon of McWhorter constitutes a portion of his balloon catheter, his teaching of the use of ePTFE for the tubular catheter shaft portion of his balloon catheter (Fig. 1, ref. no 38) has absolutely nothing to do with the inflatable balloon portion of his balloon catheter (Fig 1, ref. nos. 28 and 29) which is very clearly elastic. The present claims relate to the use of porous PTFE, an inelastic material, rendered non-porous by the use of a non-porous coating (e.g., FEP) for use as the inflatable balloon component of a balloon catheter. McWhorter's teaching of the use of

ePTFE for the non-inflatable tubular catheter shaft of his balloon catheter is in no way suggestive of the presently claimed use of ePTFE for an inflatable balloon. An inflatable balloon must have a compacted state (having a small internal volume) for insertion into a body conduit and subsequently inflated to a larger diameter (and volume) for a therapeutic purpose. McWhorter does not suggest in any way that his tubular catheter shaft will change in diameter during inflation of his elastic balloon component; indeed, if his tubular shaft changed in volume during inflation it would preclude inflation of his balloon component and render it inoperable.

Karwoski et al. teach the use of fluorinated coatings to improve the biocompatibility of vascular grafts, primarily Dacron (polyethylene terephthalate) vascular grafts. Their coating has a thickness of up to 500 angstroms, or 0.05 microns (col. 2, lines 59-60). The ePTFE described in the present application, rendered non-porous for use as the catheter balloon, generally has a fibril length (relevant to pore size) of about 5 to about 120 microns (specification at page 7, lines 31-33). The maximum coating thickness of Karwoski et al. is thus two orders of magnitude smaller than the smallest fibril length of the ePTFE taught for the present invention; it would not be capable of coating the ePTFE to render it non-porous. While Karwoski et al. teach that their coating may be used on both porous and non-porous substrates, they do not suggest in any way that their coating might be useful for rendering any porous substrate non-porous.

Because neither reference teaches or suggests the use of porous PTFE rendered non-porous by a coating for a catheter *balloon*, the present claims are not obvious in view of the cited references, wither alone or in combination.

CONCLUSION

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

If any questions remain, applicants request that the Examiner telephone the undersigned practitioner.

Respectfully Submitted,

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